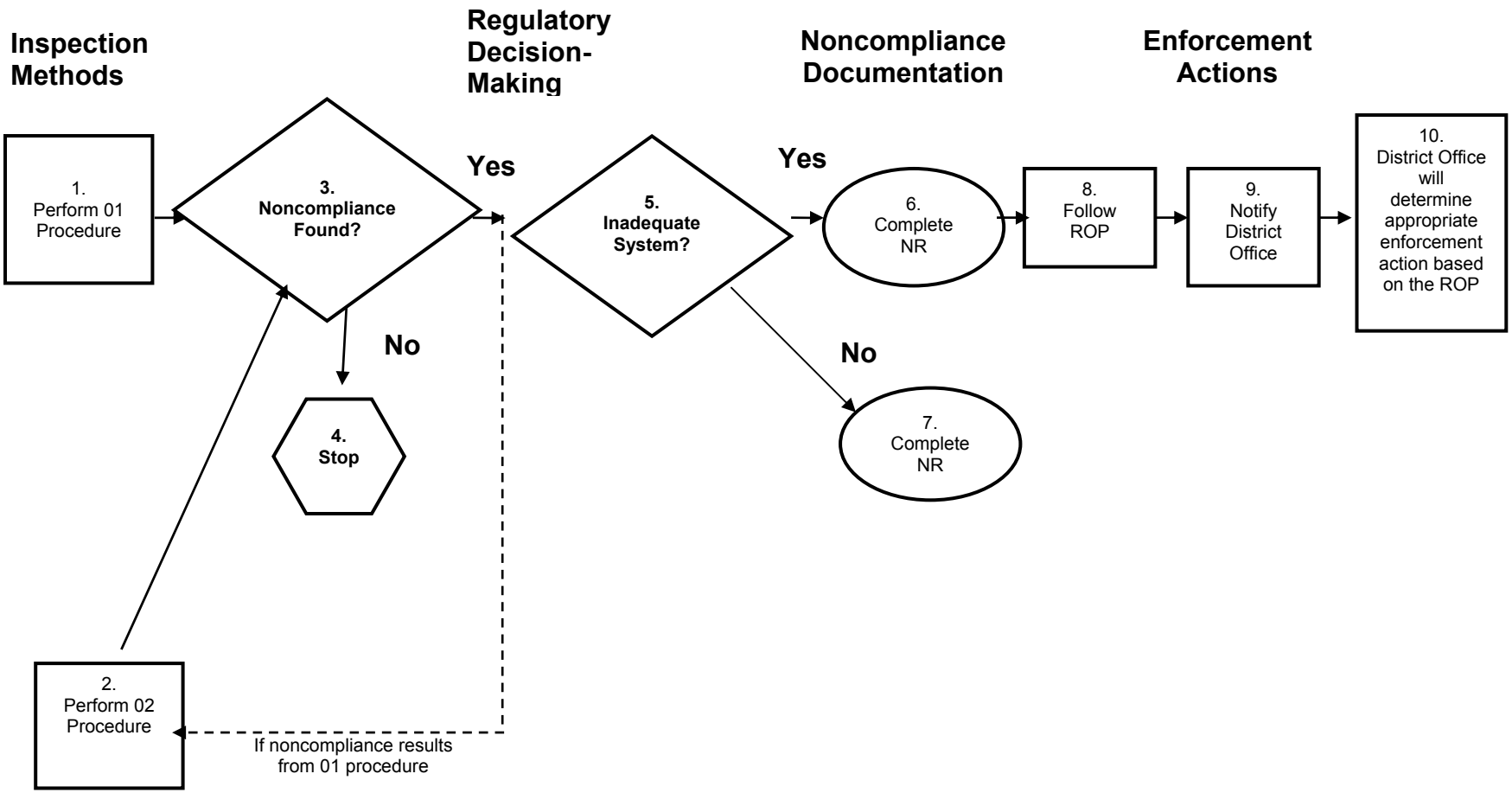
Regulatory Process for HACCP



HACCP: NRTE/RTE Documentation and Enforcement

Documentation

Recall that to get to this step, you gathered information to seek answers to your questions and assessed information so that you are now able to make a sound decision to determine compliance.

There are several responsibilities related to documentation that you must perform. They include (1) **updating the plant profile** with the appropriate processing categories that apply to the product produced by the establishment, (2) **documenting the procedures you perform** on the Procedure Schedule, and (3) **documenting all regulatory noncompliance.**

(1) Updating the Plant Profile with the appropriate processing category

When a plant begins operation or adds a new product, the Plant Profile must be updated to show the processing categories that apply to the product produced by the establishment. Your responsibility is to determine the most likely category for the product and use that to enter a process category into PBIS for the system to schedule procedures for you to perform. You can look at the finished product and labeling to assist you in determining the process category. The process categories in the NRTE/RTE are:

- Fully cooked – not shelf stable (03G)
- Heat treated but not fully cooked – not shelf stable (03H)
- Products with secondary inhibitors – not shelf stable (03I).

Select the appropriate processing category and complete the related form (electronic). This information is used to schedule procedures for the establishment.

(2) Documenting procedures performed on the Procedure Schedule

For each procedure scheduled, you must indicate whether it is performed or not performed on the Procedure Schedule.

Only mark scheduled procedures as “not performed”. It is not appropriate to list an unscheduled procedure as “not performed”. If it is not scheduled, you do not mark anything until the 02 procedure is completed. If the procedure is on the schedule that day, you can mark it. If the appropriate 02 procedure is not scheduled on the day you complete it, then record your findings as unscheduled.

Here's an example of documenting an 02 procedure for an RTE product. Let's say you have 03G01 scheduled today. You select the semi-dry, keep refrigerated salami. While performing your procedure, you discovered a noncompliance that triggered you to perform the 03G02. However, the specific production for the salami is only about two-thirds of the way through the entire process (for the HACCP plan that covers the salami). You start the 02 procedure today, but since you won't be completing it today and an 03G02 was not scheduled to be performed (this procedure was triggered due to noncompliance in 03G01), do not record anything for this 02 on the PBIS Procedure Schedule (PS). At the end of next week, when the pre-shipment review is completed for that specific production, you need to record on the PS that you completed the 03G02. If there is an 03G02 already scheduled on that PS the day you complete the 03G02, then mark it according to your findings of compliance/ noncompliance. If 03G02 is not on the PS for the day you complete the procedure you started the week before, then document 03G02 as unscheduled on the PS.

(3) Documenting noncompliance

Any noncompliance you find must be documented on the FSIS Form 5400- 4, Noncompliance Record (NR). The NR is a legal document that is the first step in any enforcement documentation trail. It is vital that you write each finding clearly and concisely.

When you perform one of the HACCP procedures and determine that there is regulatory compliance, document that the procedure is performed on the PS. When you determine that the plant does ***not*** meet one of the regulatory requirements, you not only document that the procedure is performed on the PS, you also document the noncompliance on an NR. Use the appropriate trend indicator. The four trend indicators for HACCP are monitoring, corrective action, recordkeeping, and plant verification. Only one trend indicator is used for each NR issued. When noncompliance is documented, you do not record the procedure as "performed" on the PS. Instead, you record the noncompliance on the PS.

Since you issue an NR on all FSIS-discovered noncompliance, an FSIS test result of a positive for 05B02 sampling is a definite noncompliance that was discovered by FSIS.

Trend Indicators

There is no trend indicator for 03A01 (Basic noncompliance). You mark "HACCP" only in block 9 of the NR.

There are four trend indicators used for documenting noncompliance with HACCP regulatory requirements.

1. Monitoring
2. Corrective Action
3. Recordkeeping, and
4. Plant Verification

Notice that these correlate to the five regulatory requirements with the exception of reassessment. Reassessment noncompliance is documented as either corrective action (417.3(b)(4)) or recordkeeping noncompliance trend indicators.

Monitoring Trend Indicator

Use the monitoring trend indicator when you determine that there is noncompliance with the monitoring requirement. Mark this trend indicator when

- The plant is not monitoring the critical limit at the frequency stated in the HACCP plan.

- The plant is not monitoring the critical limit using the procedures described in the HACCP plan.

- You find a deviation from the critical limit that the plant has no way of detecting. (For example, you verified the monitoring requirement by taking a cooked product temperature of patties coming out of the cooking unit. You find that the critical limit is not met.)

- If you find a noncompliance that is attributed to an unforeseen hazard, document the noncompliance under HACCP monitoring, because the plant was not monitoring sufficiently to discover such a hazard on its own (monitoring was not sufficient to demonstrate process control).

You also use the monitoring trend indicator when there is an unforeseen hazard (not part of the HACCP plan). This implies that the monitoring is not sufficient to detect food safety hazards that may occur.

Corrective Action Trend Indicator

The corrective action trend indicator is used when a deviation or an unforeseen hazard occurs, and the plant's corrective action does not meet the regulatory requirements. Also use the corrective action trend indicator if the corrective actions taken in response to a deviation from a critical limit did not:

- Appropriately address, identify and eliminate the cause of the deviation.
- Include measures to ensure that the CCP is under control.
- Include measures to prevent the deviation or unforeseen hazard from recurring.
- Include appropriate disposition of the product.

Note: For this trend indicator, only document a plant's failure to meet the requirements of §417.3. If the plant finds the deviation or unforeseen hazard and takes the corrective action necessary to meet the regulatory requirements, there is no noncompliance.

Recordkeeping Trend Indicator

Use the recordkeeping trend indicator when the:

- Monitoring records do not include the actual times, temperatures, or other quantifiable values; the calibration of process-monitoring instruments; corrective actions; verification procedures and results; product identity; signature or initials of the person making the entry; or the date the record is made.
- Plant does not have the decision-making documents associated with selecting and developing CCPs and critical limits, or documents supporting both the monitoring and verification procedures and frequencies.
- Plant did not conduct a pre-shipment review.
- Plant is not retaining HACCP records for the required length of time.

Plant Verification Trend Indicator

Use the plant verification trend indicator when the plant is not conducting the verification activities:

- As described in the HACCP plan, or
- At the frequencies described in the HACCP plan.

You also use the plant verification trend indicator when a RTE sample is positive for a pathogen.

Documenting Noncompliance

When documenting noncompliance on a Noncompliance Record (NR), do the following.

- Identify *each* noncompliance.
- Be specific and thorough**,** including time and location.
- Explain that plant management has received notification.
- State any regulatory control actions you took.

If you are establishing linkages between NRs, then you would also:

- Include any previous corrective actions that were unsuccessful, and any applicable deadlines.
- Note the establishment response to previous notification.

The sections of the NR specific to HACCP (and not also parts of other regulatory requirements) are blocks 7 and 9b. You should already be familiar with an NR and how to properly fill-in the appropriate blocks. In block 7, you reference the page number or section of the HACCP plan that corresponds to the noncompliance. If the plan does not include this information, then you leave it blank. For example, if the plant missed a monitoring check, you reference the HACCP page or section that states the monitoring frequency. If an unforeseen hazard occurred, there probably is no reference to include.

7. RELEVANT SECTION OF	HACCP	SSOP	OTHER
8. ISP Code			

9. NONCOMPLIANCE CLASSIFICATION INDICATORS						
PLANT PROCESS	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation	
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification	

As you can see from block 9b, there is no trend indicator for reassessment. When verifying the reassessment requirement and noncompliance is observed, you might do further assessment to determine the appropriate trend indicator.

For example, if the plant was to reassess because an unforeseen hazard occurred, and the plant did not reassess, then use the *corrective action* trend indicator because reassessment is part of the regulatory requirements in §417.3(b)(4). But if the plant performed the reassessment as per §417.3(b)(4), but did not document it as part of the corrective action record, then the *recordkeeping* trend indicator is used. Also, the recordkeeping trend indicator is used if the plant performed the annual reassessment, but did not document it; or if the plant did not perform any annual reassessment.

On the NR Continuation Sheet (FSIS Form 5400-4a), which is used only when you need extra space check the box next to the word “Attachment” in the top right corner of the sheet. Complete block 7 as you did on the first page. You need to write the trend indicator in block 9, since there is no check-off box on the continuation page for the trend indicator. The rest of the 5400-4a is completed as you discussed in SSOP.

7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN	| HACCP	| SSOP	| OTHER

8. ISP CODE	9. NONCOMPLIANCE INDICATOR

Deviation versus Noncompliance

A ***deviation from a critical limit*** is the failure to meet the applicable value determined by the plant for a CCP. If a deviation from a critical limit occurs, the plant is required to take corrective actions in accordance with 9 CFR 417.3(a).

A ***HACCP noncompliance*** is the failure to meet ***any*** of the regulatory requirements of §417 (monitoring, verification, recordkeeping, reassessment, or corrective action). If the plant finds the noncompliance, and takes appropriate corrective actions and preventive measures, there is no noncompliance. If the plant does not take immediate and further planned actions on something it finds, you should document it on an NR. If you discover the noncompliance, and the plant has not, then you issue an NR. If a HACCP noncompliance occurs for which you issue an NR, the plant is expected to document its immediate and further planned actions to correct the noncompliance in blocks 12 and 13 of the NR.

Because the plant’s corrective action documentation provides the actions and preventive measures for the deviation, not writing an NR does not adversely affect your ability to track developing trends. In other words, you can use plant

records to support your decision that a trend is developing. If a plant documents and satisfactorily handles a noncompliance (for example, a missed verification), you may determine not to write an NR for that incident. If you notice the plant is habitually missing verification checks, you may use the plant's records to support your determination of a trend. Issue an NR to document your findings stating that the plant's preventive measures are not working and a trend is developing. State that failure to correct the situation could result in further enforcement actions.

The HACCP system is designed to reduce errors. If the system is working, then errors are reduced.

Scenarios all use monitoring examples. The methodology applies to problems with verification, recordkeeping, corrective actions, and reassessment as well.

Situation 1
While performing an 01 HACCP procedure records review, you find that a plant employee missed a 9:00 a.m. monitoring check. You also find that the plant found the error during its records verification, demonstrated product safety with other records, and took immediate corrective and preventive measures for the noncompliance by retraining the employee. You looked at previous NRs and determined that the plant had not missed a monitoring check in over three months.

Outcome
In this situation no NR is necessary even though there was a missed monitoring check, and you mark the 01 procedure as performed. However, if you find that adequate preventive measures were ***not*** in place, and that the missed monitoring check and correction had occurred several times within the month, you may determine that a trend for monitoring noncompliance has developed. In this case, issue an NR and discuss this trend with plant management during the weekly meeting.

Situation 2
While performing an 01 HACCP procedure records review, you find that a plant employee missed a 9:00 a.m. monitoring check and there is no indication that the plant identified the missed monitoring check. You write an NR for the 01 procedure. When you perform the 02 procedure, you find that the product was shipped without a pre-shipment review.

Outcome
In this situation you write an NR for the 02 procedure that explains this noncompliance. Next you determine whether the plant can provide other

documentation that establishes product safety. If the plant cannot demonstrate product safety, take action per §500.

Situation 3
While performing the recordkeeping component of the 01 HACCP procedure, you see that a plant employee recorded a deviation from a critical limit on the monitoring record. You verify that the corrective actions taken by the plant did meet the requirements of 417.3(a).

Outcome
There is no regulatory noncompliance, and an NR is not issued.

Situation 4
While performing an 02 procedure records review for a single lot of product, you see in the records that a plant employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. You continue reviewing the records and find that at pre-shipment review the plant identified the deviation and took the proper §417.3 corrective and preventive measures but failed to address the monitoring error.

Outcome
In this situation, write an NR for the monitoring error and determine whether the plant can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the plant cannot support product safety, take action per §500.

Basic Noncompliance

You identify basic noncompliance (03A01) whenever you make a check on the Basic checklist.

When **new federally inspected** meat or poultry plants come under inspection, or when an establishment starts producing a product under a **new processing category** and has created a **new HACCP plan** that has not yet been in operation, you may find basic noncompliance while performing procedure 03A01. In those cases,

- Complete the Basic Compliance Checklist, FSIS Form 5000-1.
- Issue an NR.
- The plant is not permitted to start production of products under the noncompliant HACCP plan. Notify the District Office.
- Attach the completed FSIS 5000-1 to the NR and file them in the NR file.

If the plant **completely revises its HACCP plan**, it is essentially a new plan. However, since the plant has been producing the products covered under the

plan, you do not necessarily stop the plant from using the revised plan. Contact the DO.

If a plant has been **operating under a given HACCP plan for some time** and you find noncompliance with a basic requirement during performance of your other verification duties, you must first determine product safety. If food safety is *not* jeopardized, contact the DO for further instruction. For example, you may be asked to issue a 30-day letter for design flaws. The DO will provide you guidance to write a 30-day reassessment letter.

RTE Sampling Documentation

The original sample request was documented on the Procedure Schedule as 05B02 when the sample was mailed. If the sample is positive for a pathogen, then the NR (Noncompliance Record) is documented under the appropriate HACCP procedure.

In block 8 of the NR, record the appropriate 03 ISP code and check the "verification" trend indicator. In block 10, document:

- ✧ Sample collection date
- ✧ Product name
- ✧ Production or lot code
- ✧ Organism or toxin found
- ✧ Sample request form number
- ✧ Whether the plant shipped product from the sampled lot

If the plant has its own testing program (included in its HACCP plan), and it receives a positive result from one of its tests, you ***do not*** issue an NR. Wait to see if the plant follows its appropriate corrective and preventive measures (§417.3(a) if it is part of a CCP, or 417.3(b) if it is part of the verification but not associated with a specific CCP). Noncompliance occurs when the plant fails to implement corrective actions that meet the requirements of §417.3.

Linking NRs

You already covered linking NRs during the sanitation modules, but it is vital to document trends of HACCP noncompliance. Linkage is necessary to support further enforcement action if necessary. Use good judgment when determining which NRs to link together. Decide whether the second noncompliance is an isolated incident or a trend of noncompliance is developing.

Ask -

- How much time has lapsed since the previous NR was written?

- Was this noncompliance from the same cause as the previous NR?
- Were the plant's further planned actions implemented?
- Were the plant's further planned actions effective in reducing the frequency of these noncompliances?
- Is the plant continuing to implement better further planned actions?

NRs should be linked as the noncompliance occurs. Do not suddenly link several NRs. For example, the plant has missed performing a verification. You document this on an NR. A week or so later, the plant again misses a verification. You refer to the first missed verification (linking) in block 10 of the NR by listing the NR number and date. If this happens again a short time later, you reference the second NR on this current NR. Therefore, NR 1 (first of the trend) is referenced on 2, 2 is referenced on 3, and so on. Each NR is the link, and your linking forms a chain of documentation for the same root cause. You should document the specific further planned actions that were not implemented or were ineffective in preventing recurrence of the noncompliance.

The answers you glean from these questions will help you make an informed decision about linking NRs. If you need clarification, contact your supervisor or the TSC.

Enforcement

Under 03A01, you take a withholding action when you determine there is basic noncompliance with a HACCP plan for an establishment coming under federal inspection, or if the plan is for a new processing category or if the plan is for a new product (with a new plan). You do not permit the plant to operate under the noncompliant HACCP plan until the plant corrects the noncompliances.

Recall that the Rules of Practice in 9 CFR 500 (ROP) provides plants with due process. They also lay out how the Agency progresses with further enforcement actions, and under what circumstances.

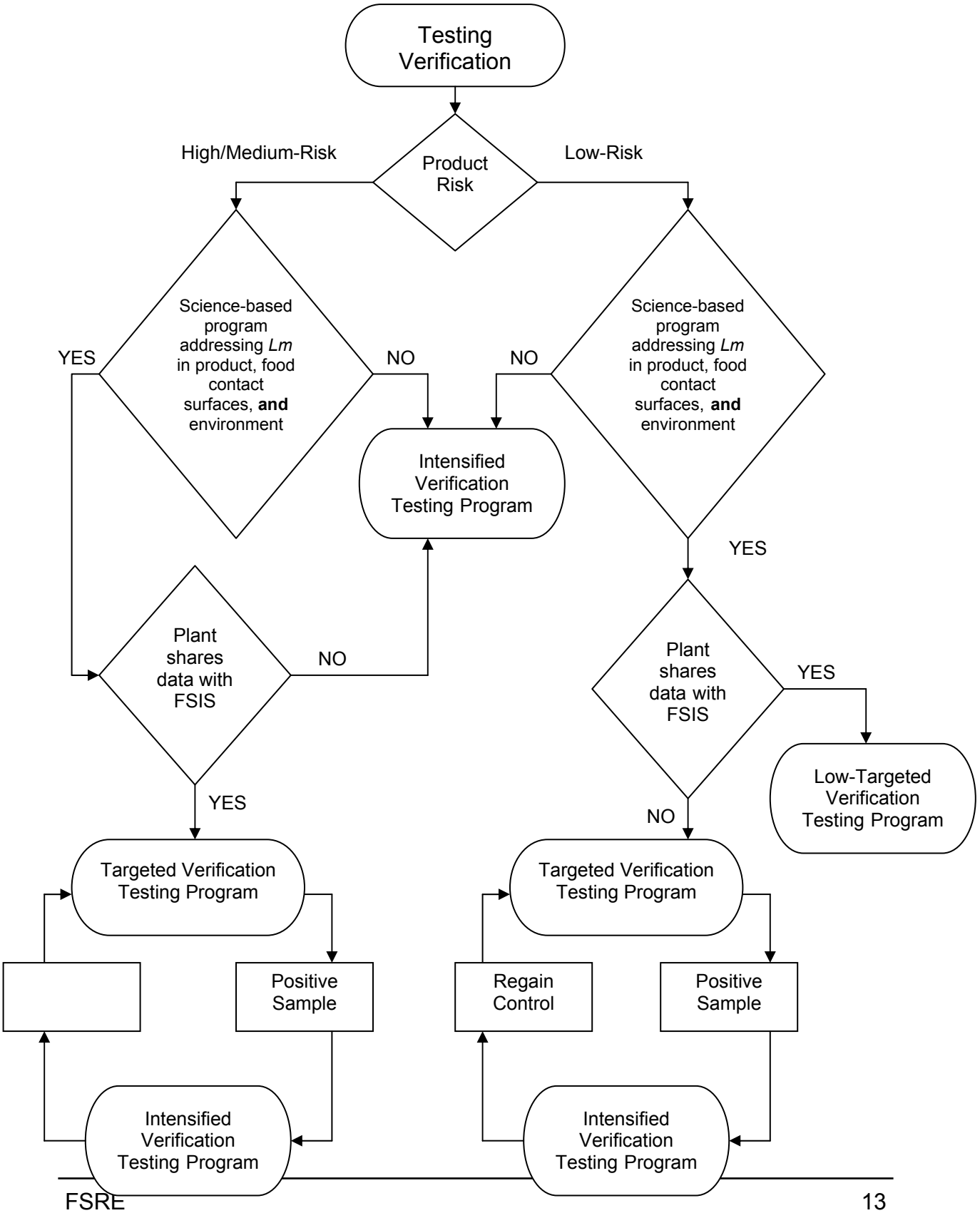
When you determine that the plant does not meet one or more regulatory requirements, document your findings on an NR. If the noncompliance involves the production and shipment of unsafe food, initiate the appropriate enforcement actions described in §500.3 (Rules of Practice). If you have documented multiple or recurring noncompliances, request that the DO issue an NOIE (Notice of Intended Enforcement Action), to the establishment as per §500.4. If you decide to issue an NOIE it should come as no surprise. By the time you have made this decision, you should have been in dialog with the establishment during weekly meetings and you should have been keeping your frontline supervisor apprised

of what was happening. Everyone (the establishment, your frontline supervisor, and the DO) should be expecting the NOIE.

In other situations, you may take a regulatory control action to prevent shipment of adulterated products. Keep your supervisor informed of any developing trends of noncompliance.

Note: 30-day letters are not an enforcement strategy. Do not confuse it with an NOIE, which is an enforcement action.

Flowchart: Determining Testing Verification Program



Enforcement Actions for Positive Microbial Lab Analyses

If product is still in the plant, determine whether or not the plant implements corrective actions that meet the requirements described in §417.3. If the plant does not control its product, then take regulatory control action (i.e., retain it). If any affected product has left the plant, and it is no longer under the plant's control, notify the DO. Give the DO the amounts of affected product that has left the establishment's control. The DO will relay the information to the RMD (Recall Management Division). RMD will request plant management to recall the affected product.

If the plant does not take control of its product, you take regulatory control action by retaining all affected product. Follow FSIS Directive 5000.1 to verify that the plant complied with §417.

Perform an 02 procedure on product records for the specific production represented by the sample, and 01B01 and 01C01 on the plant's SSOP covering the time period from when the sampled product was produced to the present. Whenever a sample is positive for a microbial hazard, there are possible sanitation problems in the establishment.

As a result of a positive sample result, additional sampling under the intensified format (any combination of RTE product, food contact surface and non-food contact surface samples) may be collected to verify the effectiveness of the plant's corrective and preventive measures (§417.3). This additional sampling should be considered on a case-by-case basis by the DO, frontline supervisor, and in-plant personnel, regardless of plant size or whether the product is in the intensified, targeted, or low targeted categories.

Product or Food Contact Surface Samples

FSIS Actions for Positive Product or Contact Surface[1] Sample and Plant Has a Science-based Program			
If plant addresses this in its…	**FSIS Sample**	**Plant Sample**	
		Plant Initiates Corrective Actions	Plant Does **Not** Initiate Corrective Actions
HACCP	Product Positive - Issue NR – document HACCP 03 procedure Trend indicator: HACCP/ Verification; 417.4 Verify plant's corrective actions; Possible recall; Perform 02 procedure	Plant takes appropriate corrective actions per §417.3(a); FSIS verifies corrective actions; Possible recall[2]	Issue NR – document as HACCP 03 procedure Trend indicator: HACCP/ Corrective action; 417.3(a) Verify plant's corrective actions; Possible recall; Perform 02 procedure
SSOP	Food Contact Surface Positive NR – 01C02/ Verification Perform 01B01, 01C01 and HACCP 03	Plant takes appropriate corrective actions per §416.15 & 417.3(b); FSIS verifies corrective actions	NR for 01B01 or 01C01; Trend indicator: SSOP/ Corrective action; Cite §416.15
SOP[3]	NA	Plant takes appropriate corrective actions per SOP; FSIS verifies corrective actions	NR for HACCP 03(E, F, G or I)01 procedure Trend indicator: HACCP/ Recordkeeping; Cite §417.5(a)(1)

[1] For *Listeria* spp., FSIS will verify corrective actions per the system or program that addresses this (HACCP, SSOP, or SOP).

[2] For **low risk** and "other RTE" products that have a post-lethality treatment subsequent to contact with the implicated food contact surface, and the treatment has been validated to further reduce the level of potential pathogens, such as *Lm*, FSIS evaluates the positive result on a case-by-case basis to determine whether to request a recall.

[3] All products should be addressed in HACCP and/or SSOP. SOP should not be used as the only product safety system in the plant.

When an **FSIS or plant's** product or food contact surface sample tests positive for *Lm*, product from the sampled lot is considered adulterated. Your enforcement actions vary depending upon whether the plant has a science-based testing program and whether or not the plant takes the appropriate corrective actions identified in its program.

FSIS Samples

If **you** collected the RTE product sample that tested positive for a pathogen, issue an NR (as per the Directive) and perform an 02 procedure on that specific production. Verify that the plant took appropriate corrective actions (under §417.3) that will prevent recurrence of *Lm* in product and will keep adulterated product from entering commerce. This may include verifying that prerequisite programs are continuing to support the decisions made in the hazard analysis and performing procedures 01B01 and 01C01 on the plant's SSOP

Additional noncompliance occurs when the plant fails to implement corrective actions that meet the requirements of §417.3.

If the plant has not already developed controls and corrective actions for *Lm*, verify that the plant reevaluates the effectiveness of the SSOP and conducts a reassessment of its HACCP plan in response to the positive finding. The plant must be able to support the decision made during reassessment.

Plant Samples

If a **plant** has a science-based program and a RTE product or contact surface sample tests positive, **NO NR** is issued unless the plant fails to take the appropriate corrective actions it had identified in its program. As you can see in the previous chart, your actions will vary depending on whether the plant has its science-based program incorporated into its HACCP plan, SSOP or a prerequisite program. If the plant does not take appropriate corrective actions, issue an NR using the appropriate HACCP or SSOP procedure code and "corrective action" trend indicator. The regulatory cite you would use on the NR would be §416.15 or 417.3 depending on where the plant's science-based program is addressed.

Note that for **low risk** and "other RTE" products that have a post-lethality treatment subsequent to contact with the implicated food contact surface, and the treatment has been validated to be lethal for *Lm*, FSIS evaluates the positive result on a case-by-case basis to determine whether to request a recall.

If the plant has not already developed controls and corrective actions for *Lm*, verify that the plant reevaluates the effectiveness of the SSOP and conducts a

reassessment of its HACCP plan in response to the positive finding. The establishment must be able to support the decisions made during the hazard analysis. A positive sample often indicates that *Lm* is likely to occur in the plant's product or environment, and that the plant should develop and implement sanitation procedures or HACCP controls if it has not already done so.

FSIS expects that a properly designed, science-based preventive program for *L. monocytogenes* to include two key points.

1.) The plant takes additional steps to thoroughly clean and sanitize potentially contaminated food contact surfaces, and
2.) Then the plant increases the number of food contact surface samples it takes, particularly of the areas represented by the initial positive, in an effort to find the source of the contamination and to prevent harborage.

If any of these follow-up samples are positive as a consequence of this searching for potential sources of contamination, verify that the plant took the corrective actions it had developed. A properly designed, science-based preventative program may include procedures such as holding and testing product after corrective actions in order to verify that harborage has been prevented. In such cases, you verify that the plant identified and implemented the conditions in which hold-and-test procedures for affected product will be initiated by the plant and the conditions in which hold-and-test procedures for affected product will be terminated by the plant.

When the plant receives a positive result and has a science-based program addressed in its SSOP, but takes no corrective actions, you use procedure 01B01 or 01C01 on the NR, depending upon which is most appropriate. Use the SSOP "Corrective Action" trend indicator and cite §416.15. If the science-based program is part of a plant's HACCP plan, then use the appropriate HACCP 03 procedure code, the trend indicator is 'Corrective Action', and cite §417.3(a). And if the science-based program is not part of either the SSOP or a HACCP plan, document the appropriate 03 HACCP procedure, along with the 'Recordkeeping' trend indicator, and cite §417.5(a)(1).

Environmental Samples

FSIS Actions for Positive <u>Environmental</u> Sample and Plant Has a Science-based Program			
If plant addresses this in its…	**FSIS Sample**	**Plant Sample**	
		Plant Initiates Corrective Actions	Plant Does Not Initiate Corrective Actions
HACCP*	NA	Plant takes appropriate corrective actions per §417.3; FSIS verifies corrective actions;	NR for HACCP 03 procedure Trend indicator: HACCP/Corrective Action; Cite §417.3
SSOP	NR 06D01 Trend indicator: Facility/Product Based Cite §416.4(b)	Plant takes appropriate corrective actions per §416.15; FSIS verifies corrective actions	NR 01B01 or 01C01; Trend indicator: SSOP/ Corrective Action; Cite §416.15
Prerequisite program	Evaluate plant's corrective actions	Plant takes appropriate corrective actions per SOP; FSIS verifies corrective actions	NR for HACCP 03 procedure Trend indicator: HACCP/ Recordkeeping; Cite §417.5(a)(1)

*Not usually addressed in a HACCP plan

When an indirect or non-food contact surface sample from the RTE production area collected by **FSIS** tests positive for *Lm*, document an NR and verify the plant's corrective actions as described in its HACCP plan, SSOP, or prerequisite program. If the plant has not addressed positive *Lm* in environmental samples, determine if the plant reassessed its HACCP plan or reevaluated its SSOP or prerequisite program. If the plant does not take the appropriate corrective actions, document accordingly. Trained inspection personnel may be directed to collect additional environmental samples, as well as food contact surface samples and product samples under the intensified verification testing program.

Recalls

The DO and possibly the RMD evaluate each situation on a case-by-case basis. The cause of the positive finding varies based on the pathogen or toxin found and the type of processing involved. More or less product may be determined "affected product" based on all considered factors (e.g., whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens or toxins are involved, whether there have been

any other incidents of contamination in the plant associated with the pathogen or toxin, and whether there have been persistent and recurring noncompliances in the plant).

The RMD is notified immediately if product has left the establishment's control, and they coordinate any recall activities. You must determine the status of the products that were produced under the same HACCP plan in the same time frame as the sampled lot and report this back to the DO. The DO notifies the RMD (see FSIS Directive 8080.1, Rev. 3, Recall of Meat and Poultry Products). RMD is notified so a press release can be issued and effectiveness checks can be performed.

Adequacy of the HACCP System

To determine the plant's HACCP system adequacy, you must look beyond just the actual written HACCP plan. All available evidence and supporting documentation must be taken into account. You should have intimate knowledge of the plant's process capabilities and use this knowledge to assist you in your determination. You should evaluate other systems within the plant (SSOP, in-plant testing programs like environmental testing or end-product testing, etc.).

For example, if an establishment has not identified L. monocytogenes as a food safety hazard likely to occur in its process and is testing outside the HACCP plan or SSOP and gets a positive result, a reassessment of its HACCP plan and hazard analysis is required in 9 CFR 417.4(a)(3). The establishment is required to support the decisions made during the reassessment as specified in 417.5(a)(1)&(2).

It is the responsibility of the CSI to verify that the establishment is meeting these requirements. If the establishment did not reassess its HACCP plan and hazard analysis as required by 417.4(a)(3) or does not have supporting documentation required by 417.5(a)(1)&(2), you cannot determine that the HACCP plan is meeting the requirements of 417.2, therefore the HACCP system may be determined to be inadequate as described in 417.6.

Remember at the beginning of the verification methodology you were told not to be afraid to ask very ***specific*** questions when you are trying to determine food safety. That thought process is something you should continue throughout your verification of the HACCP regulatory requirements. For example, construction that could impact on *L. monocytogenes* should be closely assessed. Ask what preventive measure the plant will take to prevent product contamination. Ask if the plant will do environmental testing during the construction project, and if so, what will the plant do if the results indicate any significant microflora changes during that time. Ask if the plant will implement any additional sanitation procedures during the construction project, and if it will do any testing to

determine the effectiveness of these special procedures. Be curious and always look a step beyond what you know to be sure that you understand all aspects of the plant environment and production practices that have an impact on the safety of the products produced.

Documentation, both by the plant and by you, is vital to the success of HACCP. It is difficult to determine system adequacy without documentation. Likewise, if you are trying to initiate an enforcement action based on trends or a series of problems, and you do not have the NRs or other documents, you may not be able support that enforcement action. To show a trend, you need to have linked NRs.

To properly determine the appropriate enforcement actions, you need to answer three key questions.

1. Does the HACCP plan meet the regulatory requirements of Part 417?

If the plant is not implementing all or some of its program, it has not met regulatory requirements. For example, if a plant is not maintaining **any** records associated with its HACCP plan, not monitoring critical limits at any CCP, not reassessing the HACCP plan when required, or not modifying its HACCP plan when it no longer meets the requirements then the plant has not met the regulatory requirements. You are then unable to make the determination that the plant is not producing adulterated product, and therefore the HACCP system is deemed inadequate. In these cases, the HACCP system is considered inadequate for not meeting the regulatory requirements of Part 417.

2. Was adulterated product produced or shipped?

If the HACCP system did not prevent the production and distribution of adulterated product, it is an inadequate system. If the plant failed to meet a critical limit at a CCP and did not take corrective actions per §417.3, but the plant had performed its pre-shipment review, then the HACCP system is inadequate.

3. Is there a trend in establishment noncompliance?

You should observe trends when determining whether a plant's HACCP system is inadequate. If multiple NRs have been documented for the same or similar cause, there may be a trend developing. Because there are a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily support an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in incidents of noncompliance, you must closely review the noncompliance descriptions (block 10 on the NR).

Summary for NRTE/RTE HACCP

The HACCP regulations require that establishments conduct a hazard analysis to determine if there are any food safety hazards that are reasonably likely to occur in the production of meat and poultry food products and to develop critical control points to control any hazards identified.

The culmination of the plant's work (flow chart, hazard analysis, scientific support, critical control points, critical limits, etc.) is the HACCP plan. The plan contains the procedures (CCP) and frequencies for monitoring the critical limits that have been established for each identified hazard. The plant also contains procedures and frequencies for verification of the monitoring of CCPs. The HACCP plan identifies records that will be used to document the monitoring of critical limits and to document corrective actions if there is a deviation from a critical limit. Since the hazard analysis is the foundation of the HACCP plan, anytime you have questions about the contents of the HACCP plan, you might review the hazard analysis and the decision-making documents supporting the hazard analysis and the HACCP plan.

Establishments must be able to support the decisions they made during the hazard analysis and development of the HACCP plan, when setting critical limits and when determining monitoring and verification frequencies. Anytime you have question about the contents of the HACCP plan you may want to review the decision making documents that the establishment has to support the hazard analysis and the HACCP plan. If you need help in determining whether scientific or technical supporting documentation is valid, you may contact the Technical Service Center.

The processing categories group similar products together based on processing techniques and labeling. Because the steps vary in producing the products, the hazards likewise vary. Each plant is responsible for producing product in accordance with §417.2 - 417.7. Your job is to verify that the plant is meeting regulatory requirements.

The Regulatory Process for HACCP is consistent for each processing category in which you are verifying compliance. Understanding your role in properly performing verifications of the plant's monitoring, verification, recordkeeping, corrective actions, and reassessment is vital to accomplishing the Agency's mission of ensuring a safe, wholesome, unadulterated food supply to consumers everywhere.

Documentation is key where HACCP is concerned. You rely on plant documentation to make your critical decisions about noncompliances, deviations, and the adequacy of the plant's HACCP system. The Agency relies on you for

the initial documentation to support all FSIS decisions regarding enforcement within the plant environment.

Do not be afraid to ask very ***specific*** questions when you are trying to determine food safety. You are in the plant to enforce the regulations that protect the public health. For example, construction that might encourage the incidence of *L. monocytogenes* should be closely assessed. Ask what preventive measure the plant will take to prevent product contamination. Ask if the plant will do environmental testing during the construction project, and if so, what the plant will do if the results indicate any significant microflora changes during that time. Ask if the plant will implement any additional sanitation procedures during the construction project, and if it will do any testing to determine the effectiveness of these special procedures. Be curious and always look a step beyond what you already know to be sure you understand all aspects of the plant environment and production practices that have an impact on the safety of the products produced. Often, the answers you receive will lead you to ask even more questions. You are better equipped to make sound decisions when you have all the answers to your questions. If you exclude some key questions, you may not be obtaining all the information needed for the Agency to properly assess the plant's food safety systems.

As you go about verifying the plant's compliance with regulatory requirements, think of the questions you would ask to aid you in making your determinations. What answers are you seeking and why? These are key factors in a sound decision-making process. The HACCP regulations are the Agency's design and your daily in-plant performance is the application of that design.

Workshop

Documentation and Enforcement

1. While performing an 01 HACCP procedure records review, the CSI finds that a plant monitor missed a monitoring check at CCP1, cooking. The CSI reviews previous NRs and observes several recent NRs for missed monitoring checks, most recently 4 days ago, also at CCP1. The CSI determines that these are from the same cause and decides to link this NR to the most recent previous NR. List all of the information that the CSI should include in block 10 of the NR.

2. If the CSI decides that it is appropriate to initiate an enforcement action with prior notice, describe the steps that the IIC would take.

3. You are a GS-9, who has begun a new assignment in a facility that produces fully cooked chicken nuggets. Upon your arrival at the plant you took a tour of the facility and observed that the company uses a continuous oven to cook their product. You also noted that upon exiting the oven, the cooked nuggets immediately enter a spiral freezer and are quick frozen within 20 minutes. Company records located next to the freezer indicated that the product achieved an internal temperature of 15 degrees F or lower during the freezing process.

Later in the day, as part of your familiarization with the company and its processes, the company QC Supervisor, Mr. J. Dough, conducted an awareness meeting with you where he described the plant operations; the Hazard Analysis; and the HACCP plan. He informed you that the company has identified one CCP, for lethality, at the cooking step in the Hazard Analysis. You noted that the company did address the stabilization (cooling) of the cooked chicken nuggets but had determined that there was not a hazard that was reasonably likely to occur associated with that step in the process. The company's decision was based on the fact that the company is utilizing a quick freezing process. You asked Mr. Dough if the company has any documentation on file that supports their decision. He told you that they don't have any documents because everybody knows that the product is frozen so fast that no bacteria could grow.

As a critical thinker, how would you proceed?

Give examples of the type of documentation you might expect to see as decision making documentation in the company files related to stabilization.

Is there a noncompliance?

If so, what information would you enter in Blocks 6-10 on FSIS Form 5400-4, Noncompliance Record? If an NR is needed, complete the next page with as much information as possible.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE ☐ Food Safety ☐ Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (*Name and Title)*		5. PERSONNEL NOTIFIED

1. RELEVANT REGULATION(S)

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER

8. ISP Code

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ FACILITY		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

Workshop

Documentation and Enforcement – RTE Product Sampling

1. If a RTE product tested by FSIS is found positive for a pathogen, is this an indication that the HACCP plan may be inadequate? Please discuss the thought process you would use. What actions would you take?

2. If a plant tests for indicator organisms and has a second positive result for indicator organisms, is this an indication that the plant controls and testing programs in its SSOP or SOP are not valid? Please discuss the thought process you would use. What actions would you take?

3. From Est. 38, on February 10, you sampled and mailed the frankfurters under Targeted.

   The frankfurters were positive for *Salmonella* and negative for *L. monocytogenes.*

   What action does FSIS take? List the FSIS groups involved and what each would do. Use the next page for listing these answers. If an NR is needed, complete the next page with as much information as possible. *Note: If you decide to complete an NR, not all blocks can be completed based on the information in this scenario.*

   List FSIS actions

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE ☐ Food Safety ☐ Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (*Name and Title)*		5. PERSONNEL NOTIFIED
4. RELEVANT REGULATION(S)		

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER
8. ISP Code			

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ FACILITY		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

15. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD** **CONTINUATION SHEET**		**TYPE OF NONCOMPLIANCE** ☐ **Food Safety** ☐ **Other Consumer Protection**
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (*Name and Title*)		5. PERSONNEL NOTIFIED
6. RELEVANT REGULATION(S)		
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN	| HACCP | S SOP | OTHER	
8. ISP CODE	9. NONCOMPLIANCE INDICATOR	
10. DESCRIPTION OF NONCOMPLIANCE		

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	12. DATE

FSIS FORM 5400-4a (7/98) Replaces FSIS Form 5400-4a (9/97), which may be Used until exhausted.

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1 copy - Inspector

Workshop 

Enforcement – RTE Product Sampling

1. You are a relief inspector and arrive on your new assignment, a small plant that produces a variety of ready-to-eat and not-ready-to-eat products under 03G and 03H processing categories. The plant has two separate HACCP plans. As part of your plant awareness process, you review the plant's SSOP, hazard analysis and associated HACCP plans. In addition you review the plant profile and noncompliance history from the PBIS 5.0 application on your computer. Based on your review of the information provided, you determine that this large plant would be classified as a high/medium risk operation as it does not appear to have a science-based control program to address *Listeria monocytogenes* and it produces deli-type products. Some of the products the plant produces are labeled and held frozen, causing them to fall into the low risk product designation.

You open the mail and see a directed sample request form for a targeted testing program. The instructions in block 18 of the form indicate:

* See FSIS Directives 10,240.3 (12/09/02) and 10,210.1 amend. 5 for instructions on this sampling program.
* Collect a RTE sample other than Non-Targeted as defined in FSIS Directive 10,240.3, giving priority to high and medium risk products. If the establishment produces ONLY Non-Targeted type products, DO NOT COLLECT A SAMPLE, mark the appropriate box in block 28, and mail the form to the lab in block 9.
* To be analyzed for: Listeria monocytogenes AND Salmonella. If fully cooked meat patties (318.23), or dry or semidry fermented sausage, also E. coli O157:H7.
* Complete all info requested in blocks 19, 20, 22 & 28-32. Enter NA in any required block where the info is not applicable or not available. DO NOT LEAVE REQUIRED BLOCKS BLANK. The lab cannot analyze samples with incomplete forms.

You find in the file a note from the IIC regarding plant notification when samples are submitted. The note indicates the plant needs to be notified at least one day in advance of any sample being collected to ensure it has an opportunity to hold all affected product. You ask the Plant Manager if he will be producing any deli-type products within the next few days. He indicates that no deli-type products will be produced for a few weeks. You then ask what he plans to produce today and tomorrow. He indicates that he will be producing tortellini with meat and meatballs in sauce today and two kinds of meat stromboli tomorrow. You inform him that you will be taking a RTE sample of the stromboli and are providing him with notification within the agreed upon time frame so he can decide if he wants to hold any potentially affected product or not. The plant manager asks that you

select another one of his products since he is making a special order tomorrow and needs the product to go out on time.

What do you tell him?

2. You are assigned to a plant that produces various RTE products, including sliced luncheon meats, non-sliced luncheon meats intended to be sliced at delis, and a variety of hotdog-type products. Neither the deli-type nor the hot dog-type product is formulated or produced to prevent growth of *Lm.*

a. What risk category do the products fall into?

The plant has science-based programs in place to control for *Lm* in the product, on food contact surfaces, and in the environment. These programs form the basis for decisions made in the hazard analysis of the plant's HACCP plan. The programs include SSOP procedures to test product contact surfaces for *Listeria* spp. and a prerequisite program that includes environmental testing of indirect and non-contact surfaces for *Listeria* spp. The HACCP plan includes CCPs for lethality and stabilization.

All product contact testing results are in the SSOP records. In addition, all records for the testing of indirect and non-contact surfaces are available to FSIS inspection personnel through the pre-requisite program (because these programs and records support decisions in the HACCP plan hazard analysis, they are available to FSIS through record keeping requirements defined under 417.5(a)(1)).

b. Into what FSIS testing program do these products belong?

While performing the 01C01 record verification procedure, you observe that a slicer blade resulted in a positive for *Listeria* spp. You verify (through records and/or direct observation) that the plant has followed the corrective actions outlined in its SSOP. The plant documented that it

- Reviewed past sample data and determined there were no positives for product or food contact surfaces in the past several months;
- Informed the sanitation foreman (SF) of the positive samples and the SF ensured that special care would be taken that night in cleaning and sanitizing the positive areas (including breaking down the complex machinery for thorough cleaning and placing equipment in the smokehouse for heat application of 170°F.); and

- Took additional food contact surface samples as defined in its SSOP after completing pre-op. Samples were taken before the broken down machinery was reassembled.

c. What other actions do you take?

3. You are assigned to a plant that produces various RTE products, including sliced luncheon meat and hot dogs. Neither the deli-type nor the hot dog-type product is formulated or produced to prevent growth of *Lm.* The plant has a validated post-packaging pasteurization process step within its process.

a. What risk category do the products fall into?

Continuing with the above scenario, the plant has a good compliance history in maintaining sanitation and has no history of multiple or recurring noncompliances documenting insanitary conditions (01B, 01C and 06D). It has science-based programs in place to control *Lm* in the product, on food contact surfaces, and in the environment to support decisions made in the hazard analysis of its HACCP Plan. The programs include SSOP procedures to test product contact surfaces for *Lm*, and a prerequisite program that includes environmental testing of indirect and non-contact surfaces. The plant included controls for *Lm* in the HACCP plan through a CCP for the post-packaging pasteurization process step as well as CCPs for lethality and stabilization.

b. Into what risk operation category do these products belong?

Continuing with the above scenario, plant management shares all product contact test results with FSIS by having the testing results within the SSOP records (416.16). All records for the testing of indirect and non-contact surfaces are available to FSIS through the pre-requisite programs.

c. Based on these factors, into what FSIS testing program do these products belong?

Continuing with the above scenario, while performing procedure 01C01, records verification, you review the results of the environmental testing program for indirect and non-food contact surfaces from the prerequisite program. You note that the plant found a positive *Listeria spp* from a floor drain in the RTE packaging room. Upon further review of the plant records, you discover that the plant performed corrective action as stated in its prerequisite program. The

corrective actions included additional cleaning and sanitizing in that part of the facility and additional indirect/non-food contact surface testing which resulted in a positive *Lm* finding on a non-food contact surface. You further look into what other actions the plant has conducted and find that it reviewed the floor drain cleaning procedures in production related areas. The plant decided to increase the cleaning frequency from once to twice per week. Additionally it is increasing the testing of product contact surfaces to determine if the SSOP is functioning as intended and based on those results may modify its SSOP. A review of plant records for the environmental and product contact surface testing program showed no positive findings for *Lm.*

d. How should you proceed?

4. At the same plant the following week, the plant maintenance supervisor informs you that the plant will be renovating two existing production rooms. They will remove the wall between the raw product storage cooler and the cooked product slicing room to expand the existing slicing operation. This will be conducted over the next two weekends, along with the installation of several overhead water, air and electrical lines.

They will install a new shingle stack slicing/packaging machine in the newly enlarged ready-to-eat product packaging room. A hydraulic oil line will be installed to accommodate the new slicing/packaging machine.

Modifications will be made to a floor drain in order to install a new hand wash sink and a drain line adjacent to the new slicing machine. They will correct a water leak in the ceiling (you had documented this on an NR) at the same time they install the sink.

Because of the extent of the changes, the entire area will be out of use until the renovation is complete. Entrances to the affected rooms will be sealed with plastic sheets and the QC supervisor will monitor traffic in and out of the area.

Prior to operations in the expanded area, the new equipment and the entire RTE product packaging room will be thoroughly cleaned. The QC department will perform microbial swabbing of the affected equipment and environment to further ensure its cleanliness. *(Note: The plant has elected to perform additional product contact testing outside of its normal quarterly testing frequency, to ensure the effectiveness of the special clean-up.)*

Based on this information, the day the new RTE operations are to begin, you conduct an unscheduled pre-op inspection (01B02). You notice that there is an area close to an existing wall that has plastic draped from the floor to the ceiling resembling a temporary wall. You are informed that all the work was not

completed as intended so the plant put up a temporary wall to create a barrier between the production area and the area that the construction crew was still working on. This work includes covering up the area where the old existing wall was located as well as some electrical and plumbing work, which is projected to be complete in a week or so.

The plastic is loose at a small area near the top and you are told that it is for ventilation in the work area. An area along the bottom is folded back to allow access for the construction workers since there is no other access to that area from the outside. The construction workers access the work area in the RTE room along a roped off area next to the wall.

You determine that the product contact surfaces of the new machine are visibly clean and that throughout the entire RTE production room you find no noncompliances. You observe QC collecting samples to be tested for *Listeria* species. QC takes swabs from both food contact surfaces on the new slicing machine and from non-food contact surfaces of the floor drain.

The following week, you review the company's SSOP records and test results of the environmental and special product contact surface testing from the previous week. The records indicate positive *Listeria* spp. findings from a floor drain and on a product contact surface of a slicing machine in the RTE product packaging room on the same day.

The plant followed the corrective actions stated in its prerequisite program, which included additional cleaning and sanitizing in that production area with additional indirect/non-food contact surface testing, to include *Lm* due to the *Listeria* spp. finding. The plant followed the same procedure for the positive finding on the food contact surface, since it has no written procedures to follow.

As you continue the records review, you discover that two days later the plant had a positive *Lm* finding on another product contact surface of a slicing machine. The records showed no other positive sample results, either for *Lm* or *Listeria* spp., for that same day.

The plant again performed additional cleaning and sanitizing in that production area and additional product contact and environmental indirect/ non-food contact testing in an attempt to determine the cause of the positive findings.

It collected a product sample from that day’s production to test for *Lm* after the post-packaging lethality step. The lot was held pending lab results. The product tested positive for *Lm*. The plant reprocessed it by placing it back through the smokehouse to provide a further lethality step.

The plant is continuing to perform additional cleaning and sanitizing of the RTE production area, as indicated by the records, as well as additional environmental indirect/non-product contact and product testing, however those results are not available as yet.

Based on all this information, how should you proceed?

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